TREATMENT OF CANDIDAL VAGINITIS : A PROSPECTIVE RANDOMIZED STUDY COMPARING TOPICALLY APPLIED MICONAZOLE WITH ORAL FLUCONAZOLE

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SUMMARY

Vaginal candidiasis infection is a common gynaecological problem. It is very difficult to eradicate the infection because of its high rate of recurrence. Some recently marketed imidazoles and triazoles have proved to be effetive when given topically for 1-3 days instead of traditional 7 days' therapy. The present study highlighted the comparative efficacy of a topically applied vaginal miconazole depot tablet with that of orally administered fluconazole in prospective clinical trial.

INTRODUCTION

Monilial vulvovaginitis has been treated with traditional topical application of antimycotic agents designed for the systemic treatment of genital mycoses including yeast fungi. The present study aimed at the comparative effectiveness of topical vaginal miconazole nitrate tablet with that of orally administered fluconazole.

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MATERIAL AND METHOD

The study was conducted in the OPD of Eden Hospital. During last one year two hundred women attended the Gynae O.P.D. with clinical and microscopically confirmed cases of monilial vaginitis. They were randomly allocated to an orally administered fluconazole (150 mg.) capsule or a topically administered 200 mg. miconazole vaginal depot tablet. Both the above regimens were given as single dose.

INCLUSION CRITERIA

Women aged 18 yrs. or above with characteristic features of vaginal candidiasis.

The patients complained of either pruritus or white discharge or both and the clinical diagnosis was confirmed by microscopy.

EXCLUSION CRITERIA

1. Pregnant and lactating women.
2. Women with veneral diseases, trichomoniasis, chlamydial infection.
3. Patients with non-specific vaginitis.
4. Patients using any anti-fungal therapy.
5. Patients sensitive to azole containing drugs.

1st follow-up visits were scheduled 1-2 wks. after the recuritment visit, 2nd follow-up visits after 4 wks. and 3rd one after 12 wks.

In follow-up visits women were examined and a vaginal swab was taken for microscopy. Clinical cure is defined as the disappearance of the clinical signs and symptoms of candidal vaginitis from one visit to the next and negative vaginal swab. Clinical recurrnce was defined as the reappearance of symptoms and signs after a symptom-free-interval. clinical failure was defined as the persistence of clinical signs and symptoms of fungal vaginitis from one visit to the next.

RESULTS

Out of 200 case evaluated in this study, half were treated with miconazole topical application and rest with fluconazole (150 mg.) oral medication. The clinical and mycological cure rates were significantly higher with oral fluconazole treated group than with miconazole vaginally treated

TBLE I
RESULT OF TREATMENT

	CURE RATE AT 3 MONTHS	PREFERENCE RATE
FLUCONAZOLE	68%	85%
MICONAZOLE	35%	30%

TBLE II
RESULT OF COMPLICATIONS

	NAUSEA & VOMITTING	HEADACHE	SKIN RASH	VARGINAL BURNING SENSATION
FLUCONAZOLE	3	2	1	X
MICONAZOLE	X	X	X	3

group after 4-5 wks. of treatment. The long term cure rate after 3 months were 68% with fluconazole group and 35% with miconazole group. Anderson et al (1989) reported 72% long-term mycological cure rate with fluconazole treated group.

When enquired about the preference about the route of administration of the medication, 85% preferred fluconazole oral treatment and 30% preferred miconazole topical applications.

In fluconazole oral treated group 3% had nauses and vomiting, 2% had headache, 1% had drug induced skin rash.

In miconazole treated group 3% had burning sensation in the vagina.

CONCLUSION & DISCUSSION

Fungal vaginitis is a very common problem which is very difficult to be completely cured because of its high rate of recurrence. Approximately 75% of women suffer from vaginal candidiasis at least once during their life time (Patel 1992). Two decades back it was treated with lotio-gention violet (1%). which was subsequently replaced by recently introduced imidazoles and triazoles. Systemic administration of imidazoles can cause serious side effects like hepatitis and affection of serum lipids. But Fluconazole used in our study was not associated with any major complications excepting some minor side effects as illustrated in the above. Considering the entire gamut of applications it may be concluded that oral fluconazole is a simple and effective substitute to the topical treatment of vaginal candidiasis. So every gynaecologist should use oral fluconazole instead of cumbersome vaginal miconazole when the patients opt for the former.

REFERENCES

1. *Anderson et al Brit. J. Obstet & Gynec. 96: 226,1989.*
2. *Patel H.S. The annals of Pharmacotherapy 26 : 350, 1992.*